

2214 '99 GCT 27 P12:25

October 12, 1999



The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street S.W. Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Prost-X contains the substances produced by the prostate gland such as acids, enzymes, and hormone precursors.*
- (2) It also helps metabolize calcium.*

These statements are made for a dietary supplement containing a proprietary blend of tillandsia usneoides, calcium glycerophosphate, and bovine prostate PMGTM extract. Other ingredients include gelatin, honey, water, natural colors, and calcium stearate. And the name of the product is Prost-XTM.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

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